

## **REMARKS**

### **Status of the Claims**

Claims 1-6, 8-13, 20 and 23-27 are pending in the present application as of the date of the mailing of the Final Office Action, with claims 1 and 20 being independent claims. Applicants previous amendments, as part of a response to the Final Office Action, were not entered. With this paper, Applicants again amend claims 1, 9, 10, 20, and 25. Claim 8 is canceled without prejudice. Reconsideration of the pending claims is cordially requested.

### **Claim Amendments**

Claim 1 is amended to include the element of “a natural biological tissue slice.” Support for the amendment can be found throughout the present application, though Applicants specifically point to Examples 1, 2, and 3 that describe the use of natural bovine tissue slices (e.g., anterior cruciate ligament, meniscus, and cartilage). Claim 1 is also amended to include “a retaining element for securing the natural biological tissue slice to the tissue site.” Support for the amendment is found in paragraphs [0038] and [0039] of the present application, and former claim 8. Accordingly, claim 8 is now canceled, with claim 9 amended to depend from amended claim 1. Claim 10 is corrected to remove an erroneous, redundant phrase from the text. Method claim 20 is amended to include the “natural biological tissue slice” of claim 1. The method is also amended to include the step of “securing the natural biological tissue slice to the tissue site.” Correspondingly, claim 25 is amended for consistency with amended claim 20. Applicants reserve the right to pursue the former claims in a follow-on continuing application.

### **Response to Advisory Action of March 7, 2006**

Applicants particularly point out that amended claim 1 not only imports a recitation from former claim 8, but also recites a *natural* biological tissue slice. Such a recitation provides further distinction over the cited art since none of the references utilizes a *natural* tissue slice, as further discussed herein. Thus, amended claim 1 is not merely a recitation of former claim 8 as suggested in the Advisory Action. Reconsideration of amended claim 1, in light of the comments provided herein, is respectfully requested.

**Novelty**

The Examiner maintains that claims 1-10, 20 and 23-25 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 6,110,212 to Gregory (herein “Gregory”). The reference, however, does not teach a “natural biological tissue slice” as recited in claim 1. Accordingly, Gregory cannot anticipate the claims.

Applicants’ response to the office action of June 17, 2005, clearly distinguished Gregory from independent claim 1, showing that the elastin or elastin-based biomaterials disclosed by Gregory are *distinct* from tissue, and thus cannot constitute a “biological tissue slice” as formerly recited in the claim. The Examiner does not deny that the structures revealed in Gregory are distinct from tissue, but maintains that the phrase “biological tissue slice” has been interpreted as a noun, and not as a descriptive structural element. As such, the Examiner appears to assert that an artificial, elastin-based biomaterial is a “biological tissue slice.”

Applicants disagree with the Examiner’s characterization of the phrase “biological tissue slice.” In order to expedite prosecution of the present application, however, Applicants amend claim 1 to recite “a *natural* biological tissue slice.” As amended, claim 1 is clearly distinguished from the teachings of Gregory. Indeed, the elastin-based (i.e., non-tissue, extracellular-protein-matrix-based) biomaterials of Gregory, such as the *artificially-formed*, three-dimensional stromal cell systems, can in no way be interpreted as *natural*.

Furthermore, as discussed in Applicants’ response to the Office Action of June 17, 2005, Gregory in no way discusses the use of a slice of biological tissue dimensioned so that cells of the tissue slice can migrate out of the slice as recited in claim 1. The Examiner’s response stated that such language was interpreted as functional language that has “not been given patentable weight.” The language, however, should be accorded patentable weight. As discussed in the Manual of Patent Examining Procedure §2173.05(g):

“A functional limitation *must be evaluated and considered, just like any other limitation of the claim*, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step.” (emphasis added)

Contrary to the Examiner's statement, the natural biological tissue slice "being dimensioned so that cells can migrate out of the tissue slice to proliferate and integrate with tissue at the injury or defect" is not a statement of intended operation having no significance. Tissue slices dimensioned so that a cell *cannot* migrate out of the tissue slice would not literally read on the claim. As such, the functional phrases of the claims should be accorded proper consideration and weight. Finally, Applicants note that the pending claims are clearly either product claims (claims 1-6 and 9-13) or method claims (claims 20 and 23-27). There are no product by process claims - and the limitations of the product claims are proper functional limitations.

In light of these amendments and remarks, amended claim 1 is clearly novel over Gregory. Claims 2-6 and 9-13, being dependent from amended claim 1, are also novel for at least the same reasons. As well, claims 2-6 are also novel over Gregory because the additional elements in each claim distinguish over the cited art, as previously discussed in the Applicants' last response. As previously mentioned, claim 8 is canceled in light of the amendment to claim 1. Method claim 20 recites the step of "providing a biocompatible tissue implant comprising a natural biological tissue slice . . . dimensioned so that the cells can migrate out of the tissue slice." As such, claim 20, and dependent claims 23-25 therefrom, are novel over Gregory for at least the same reasons that claim 1 is novel.

### **Nonobviousness**

Claims 11-13, 26 and 27 currently stand rejected under 35 U.S.C. §103(a) as being unpatentable over Gregory in view of U.S. Patent 6,773,458 B1 to Brauker et al. (herein "Brauker"). The claims, however, are all patentable because Brauker, like Gregory, fails to teach the element of a "natural biological tissue slice" as recited in the claims.

Independent claims 1 and 20 each recite a biocompatible tissue implant comprising "a *natural* biological tissue slice having a geometry suitable for implantation at the tissue site [and] dimensioned so that the cells can migrate out of the tissue slice." As discussed earlier, Gregory does not include this element. Brauker also fails to provide any hint or suggestion of this element, as discussed in Applicants' response to the previous office action. Thus, the combination of Gregory and Brauker cannot render claims 1 or 20 obvious.

Furthermore, as discussed in Applicants' response to the Office Action of June 17, 2005, no motivation exists to combine the cited art because Brauker is directed to using a barrier to contain the implant cells that is "impermeable to the vascular structure that forms

close to the boundary” (see *id.*, column 9, lines 43-44). As implied by Brauker, the pores of the boundary must be sufficient to prevent the implant cells from entering the host (see *id.*, from column 9, line 51 to column 10, line 14). Thus, Brauker teaches away from a tissue implant having a natural biological tissue slice “dimensioned so that cells can migrate out of the slice to proliferate and integrate with tissue.” Indeed, combining Gregory and Brauker would suggest a device or method that isolates a biocompatible elastin structure from the tissue of an implant site.

Accordingly, the combination of Gregory and Brauker cannot render independent claims 1 and 20 obvious. Since claims 11-13 depend from claim 1, and claims 26 & 27 depend from claim 20, these claims are also patentable for at least the same reasons that claims 1 and 20 are patentable.

**Request for Telephone Interview**

Applicants’ representative has twice attempted to reach the Examiner by telephone, leaving messages but not receiving any reply. The Applicants’ representative respectfully requests a telephone interview with the Examiner to help sharpen the outstanding issues pending in the present application.

**CONCLUSION**

In view of the amendments and remarks above, Applicants submit that claims 1-6, 9-13, 20 and 23-27 are in condition for allowance, and allowance thereof is respectfully requested.

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Respectfully submitted,

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